510(k) SUMMARY

K123077

MAY 1 4 2013

Date: September 27, 2012

Submitter:

Name:	HEBUmedical GmbH
Address:	Badstrasse 5 78532 Tuttlingen Germany
Contact Person:	Thomas Butsch
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Product:

Trade Name:	Vascular Clamps
Common Name:	Vascular Clamp
Classification Name:	Vascular Clamp

Predicate Device:

- K992053 - Aesculap Vascular Instruments
- K072834 - Sibel Vascular Clamp

Device Description: HEBUmedical Vascular Clamps are reusable stainless steel ring-handled clamps provided in a wide variety of shapes, sizes and lengths to accommodate the individual needs of the surgeon and the procedure, based on the anatomy of the site and type of occlusion. The length and angles are design features that can be important to keep the handles and shanks out of the field of vision of the operative site. The handle is provided with a ratchet closure, which permits the surgeon to adjust the amount of tension applied to the vessel. The device is provided non-sterile for sterilization by the user.

Indications for Use: Vascular Clamps are indicated for use for temporary or partial occlusion of blood vessels during open surgical procedures.

Technological Characteristics Bench testing was performed to assess clamp force and occlusion. The device has similar technological and performance characteristics as the predicate devices, as shown by the following summary table:

Manufacturer	HEBUmedical	Surgical Instruments Belgium	Aesculap
Design	Multiple jaw tips and orientation, ratchet lock on handle, ring handle	Multiple jaw tips and orientation, ratchet lock on handle, ring handle	Multiple jaw tips and orientation, ratchet lock on handle, ring handle
Principle of Operation	Clamp jaw is applied to the vessel. The amount of tension applied to the vessel for occlusion or partial occlusion is adjusted by means of the ratchet closure	Clamp jaw is applied to the vessel. The amount of tension applied to the vessel for occlusion or partial occlusion is adjusted by means of the ratchet closure	Clamp jaw is applied to the vessel. The amount of tension applied to the vessel for occlusion or partial occlusion is adjusted by means of the ratchet closure
Material	Stainless Steel	Stainless Steel, Titanium	Stainless Steel
Sterility	Non-sterile	Non-sterile	Non-sterile
Reusable	Yes	Yes	Yes

Conclusion: The information provided in this 510(k) submission provides reasonable assurance that the subject device *Vascular Clamps* is safe and effective and that it is substantially equivalent to the predicate device with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2013

HEBUmedical GmbH
Attention: Angelika Scherp
Regulatory Affairs Consultant
Badstrasse 8
78532 Tuttlingen, Germany

Re: K123077
Trade Name: Vascular Clamps
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: April 24, 2013
Received: May 7, 2013

Dear Ms. Scherp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K123077

Device Name: VASCULAR CLAMPS

Indications for Use: Vascular Clamps are indicated for use for temporary or partial occlusion of blood vessels during open surgical procedures.

Prescription Use __X__ AND/OR **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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